Premarket Notification

0910-0120

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and the implementing regulation 21 CFR part 807, subpart E, require a person who intends to market a medical device to submit a premarket notification submission to the Food and Drug Administration at least 90 days before proposing to begin the introduction, or delivery for introduction into interstate commerce, for commercial distribution of a device intended for human use. Based on the information provided in the notification, FDA must determine whether the new device is substantially equivalent to a legally marketed device, as defined in 21 CFR 807.92(a)(3). If the device is determined to be not substantially equivalent to a legally marketed device, it must have an approved premarket approval application (PMA), Product Development Protocol, or be reclassified into Class I or Class II before being marketed. The FDA makes the final decision of whether a device is equivalent or not equivalent.

The Food and Drug Administration (FDA) is requesting approval for the information collection requirements contained within 21 CFR part 807, subpart E. These requirements are:

Premarket notification submission (807.87)—*Reporting*
Section 807.87 lists the information required in each premarket notification (510(k)) submission. Each submission should contain the following information:

- Device name
- Establishment registration number, if applicable, of the owner or operator submitting the premarket notification submission
- Device class
- Action taken under section 514 of the FD&C Act for performance standards
- Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied.
- A statement indicating that the device is similar to and/or different from other products of a comparable type in commercial distribution, accompanied by data to support the statement.
- For devices that have undergone a significant change or modification, data to show that the manufacturer has considered consequences and effects that a

change, modification, or new use might have on the safety and effectiveness of the device

- A 510(k) summary as described in 807.92 or a 510(k) statement as described in 807.93 (burden included in 807.92 and 807.93, respectively).
- A financial certification or disclosure statement or both, as required by 21 CFR part 54
- For submissions claiming substantial equivalence to a device which has been classified into class III that was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990 and for which no final regulation requiring premarket approval has been issued under section 515(b) of the FD&C Act, a summary of the types of safety and effectiveness problems associated with the type of devices being compared and a citation to the information upon which the summary is based (class III summary). The 510(k) submitter shall also certify that a reasonable search of all information known or otherwise available about class III device and other similar legally marketed devices has been conducted (class III certification), as described in 807.94.
- A statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.
- Any additional information regarding the device requested by the Commissioner that is necessary for the Commissioner to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution.

510(k) summary (21 CFR 807.92)—*Reporting*
Section 807.92 specifies information required in a premarket notification summary.

510(k) statement (21 CFR 807.93)—*Reporting*
Section 807.93 specifies content and format of a 510(k) statement.

FDA is also requesting OMB approval for the following forms:

- Form FDA 3514 "CDRH Premarket Review Submission Cover Sheet" http://inside.fda.gov:9003/downloads/Administrative/Forms/FDA/UCM026058.pdf
- Form FDA 3541 "Premarket Notification [510(k)] Status Request and Response" http://inside.fda.gov:9003/downloads/Administrative/Forms/FDA/UCM014280.pdf
- Form FDA 3654 "Standard Data Report for 510(k)s" http://inside.fda.gov:9003/downloads/Administrative/Forms/FDA/UCM012986.pdf

A premarket notification is required to be submitted by a person who is:

- Introducing a device to the market for the first time; or

- Introducing or reintroducing a device which is significantly changed or modified in design, components, method of manufacturer, or the intended use that could affect the safety and effectiveness of the device.

Section 510(k) of the FD&C Act allows for exemptions to the 510(k) submissions, i.e., a premarket notification would not be required if the FDA determines that premarket notification is not necessary for the protection of the public health, and these are specifically exempted through the regulatory process. Additionally, under 21 CFR 807.85, "Exemption from premarket notification," a device is exempt from premarket notification if the device intended for introduction into commercial distribution is not generally available in finished form for purchase and is not offered through labeling or advertising by the manufacturer, importer, or distributor for commercial distribution, and the device meets one of the following conditions: (1) It is intended for use by a patient named in order of the physician or dentist (or other specially qualified persons) or (2) It is intended solely for use by a physician or dentist and is not generally available to other physicians or dentists. A commercial distributor who places a device into commercial distribution for the first time under their own name and a repackager who places their own name on a device and does not change any other labeling or otherwise affect the device, shall be exempted from premarket notification if: (1) The device was legally in commercial distribution before May 28, 1976, or (2)A premarket notification was submitted by another person.

Additionally, the Food and Drug Administration Modernization Act of 1997 (FDAMA) provided the authority for statutory exemption from the premarket notification requirements of the FD&C Act in section 510(l) and (m). Section 510(l) states that a 510(k) is not required for any class I device with the exception of those that are intended for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury. Section 510(m) states that a class II device may be exempted from the 510(k) requirements of that act if a 510(k) is not necessary to provide reasonable assurance of safety and effectiveness.

2. Purpose and Use of the Information Collection

The information collected in a premarket notification is used by the medical, scientific, regulatory, and engineering staffs of FDA in making substantial equivalence determinations as to whether or not devices have been determined to provide reasonable assurance of the safety and effectiveness of the device in order to demonstrate substantial equivalence and can, therefore, be allowed to enter the U.S. market. If the information were not collected, the impact to the Federal program would be negligible. The impact, however, to the public health of the U.S. would be great. The premarket notification review process allows for scientific and/or medical review of devices, subject to 510(k) of the FD&C Act, to confirm that the new devices are as safe and as effective as legally marketed predicate devices. This review process, therefore, prevents potentially unsafe and/or ineffective devices, including those with fraudulent claims, from entering the U.S. market.

The respondents to this information collection are from the private sector; business or other for-profit.

3. Use of Improved Information Technology and Burden Reduction

Section 745A(b) of the FD&C Act, added by section 1136 of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), provides statutory authority to require eCopies after issuance of final guidance (See Public Law No: 112-144). FDA implemented eCopy requirements on January 1, 2013, with the issuance of the final eCopy guidance (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf). The guidance describes how device companies must replace at least one paper copy of a device application with an eCopy and identify the required format and technical requirements of the eCopy. The eCopy program, as well as the technical standards for an eCopy, are described in the guidance. The eCopy requirements do not require or request any information that is not already submitted to the Agency and/or covered under the existing ICR and, therefore, do not change the cost or hour burden.

FDA estimates that approximately 100% of the respondents will use electronic means to fulfill the agency's requirement or request.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only agency responsible for the collection of this information, and there are no requirements for the submission of similar information. Therefore, no duplication of data exists. No data exists from any source, other than the premarket notification submitter, that can be used to provide FDA with information regarding safety and effectiveness of devices subject to this regulation. No other data can be used to monitor the introduction of the devices subject to the requirement to submit a 510(k) under section 510(k) of the FD&C Act.

5. Impact on Small Businesses or Other Small Entities

FDA estimates that 1,050 respondents are considered small businesses.

The information collection will have a minimal impact on a substantial number of small entities. FDA aids small business in dealing with the requirements of the regulations by providing guidance and information through the Division of International and Consumer Education (DICE), and through the scientific and administrative staff, workshops in which FDA Staff participate, and through the CDRH website at http://www.fda.gov/MedicalDevices/default.htm. These efforts help to assure that the burden on all manufacturers, including small manufacturers, is minimized.

6. Consequences of Collecting the Information Less Frequently

The data cannot be collected less frequently. The 1976 Medical Device Amendments to the FD&C Act require that notification be submitted at least 90 days before a device intended for human use is introduced into commerce. Ensuring compliance with the FD&C Act would not be possible if data were collected less frequently.

The information collected in the premarket notification is necessary for FDA to ensure that only those submissions for devices subject to the 510(k) requirements of the FD&C Act, which are as safe and effective as legally marketed predicate devices, are cleared for marketing in the U.S. The consequence of not obtaining this information would be that the FDA would not be able to provide a mechanism for clearing certain device types for market.

There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of 11/18/16 (81 FR 81772). No comments were received.

FDA has issued many guidance documents to assist manufacturers in preparing premarket notification submissions including many guidance documents that address preparing premarket notifications for specific types of devices. Under 21 CFR 10.115, FDA issues these guidance documents as drafts and invites comments when the guidance sets forth an initial interpretation of a statutory or regulatory requirement or when it includes changes that are of more than a minor nature. In addition, in section 10.115, FDA invites interested persons to submit comments at any time on an existing guidance, to suggest areas for guidance development, or to submit a draft guidance document to FDA for consideration. Following these procedures, FDA has used public input to review and revise existing guidance documents and to issue new guidance documents. The submitter of a premarket notification may choose an alternative to the recommendations of a guidance. FDA works with submitters to develop an alternative approach when appropriate.

Also, due to the premarket notification program's regulatory nature, FDA is constantly in contact with the respondents during the review of their submissions.

9. Explanation of Any Payment or Gift to Respondents

No payment or gifts in any manner or form shall be provided to respondents to this information collection.

10. Assurance of Confidentiality Provided to Respondents

Confidentiality of information submitted to FDA under a premarket notification is governed by the provisions of 21 CFR part 20 and section 807.95, and is mandated. However, the purpose of the 510(k) summaries or 510(k) statements submitted in a premarket notification is to make information available to the public within 30 days if a device has been cleared for marketing through the 510(k) process. These provisions do not permit disclosure of information in a premarket notification submission that is trade

secret or commercial confidential unless that information has been previously disclosed or as permitted under the Federal Freedom of Information Act. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. Information provided under this collection is handled in a manner to comply with the FDA regulations on public information in 21 CFR part 20. Data will be kept private to the fullest extent allowed by law.

11. Justification for Sensitive Questions

This information collection does not include questions pertaining to sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

Any person/manufacturer who proposes to begin commercial distribution of a device intended for human use into interstate commerce is required to send a premarket notification submission to FDA at least 90 days in advance of marketing. Based on trends experienced in the past 3 years, an estimated 3,900 submissions are expected each year. FDA's administrative and technical staff, who are familiar with the requirements for submission of premarket notifications, estimate that an average of 90 hours are required to prepare a submission. There is a variance in the preparation of the premarket notification submission because of the vast and varying complexities of medical devices. This includes preparation and writing of the submission and responding to any requests from FDA for supplemental information.

FDA has created FDA Form 3514, a summary cover sheet form, to assist respondents in categorizing 510(k) information for submission to FDA. This form also assists respondents in categorizing information for other FDA medical device programs premarket approval applications (OMB No. 0910-0231), investigational device exemptions (OMB No. 0910-0078), and humanitarian device exemptions (OMB No. 0910-0332). The total burden (978 hours) for FDA Form 3514 has been included in this information collection. A reference in each of the OMB Information Collections mentioned above will indicate that the overall burden for this form has been recognized in this collection (OMB No. 0910-0120). Based on a number of reviews of the summary cover sheet during the past 2 years, FDA estimates that it will receive 1,956 summary cover sheets a year. Approximately 30 minutes are needed to complete the summary cover sheet.

FDA has created FDA Form 3541, to assist 510(k) submitters in requesting information on the status of the review of their 510(k) submission. Based on a review of the number of status requests in the past 2 years, FDA estimates that it will receive about 218 status requests in a year. The respondent must complete some basic identifying information about the 510(k) and then fax or mail it to FDA. FDA estimates that completing the form and mailing it to FDA will take about 15 minutes.

Section 204 of FDAMA amended section 514 of the FD&C Act (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions including premarket notifications or other requirements. FDA has published and updated the list of recognized standards regularly since enactment of FDAMA and has allowed 510(k) submitters to certify conformance to recognized standards to meet the requirements of § 807.87. Certification of conformance to a recognized standard may allow a manufacturer to submit an Abbreviated 510(k). FDA has created FDA Form 3654 to standardize information submitted on the use of standards in support of a 510(k) submission. FDA believes that the use and full completion of this form will simplify the process for 510(k) submitters who choose to use standards in support of substantial equivalence, as well as the review and a complete documentation process for FDA. Based on a review of 510(k) notifications processed in the last fiscal year, FDA estimates that it will receive about 2,700 submissions a year and it will take 10 hours to complete this form.

Under 807.87(h), each 510(k) submitter must include in the 510(k) either a summary of the information in the 510(k) as required by 807.92 (510(k) summary) or a statement certifying that the submitter will make available upon request the information in the 510(k) with certain exceptions as per 807.93 (510(k) statement). If the 510(k) submitter includes a 510(k) statement in the 510(k) submission, 807.93 requires that the official correspondent of the firm make available within 30 days of a request, all information included in the submitted premarket notification on safety and effectiveness. This information will be provided to any persons within 30 days of a request if the device described in the 510(k) is determined to be substantially equivalent. The information provided will be a duplicate of the 510(k) submission including any adverse safety and effectiveness information, but excluding all patient identifiers and trade secret and commercial confidential information.

The estimate of burden for this collection of information is shown in the following table:

Table. 1—Estimated Annual Reporting Burden

Activity and 21 CFR Part/ Section	Form Number	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
510(k) submission (807 subpart E)		3,900	1	3,900	79	308,100
Summary cover sheet (807.87)	FDA 3514	1,956	1	1,956	0.5	978
Status request (807.90(a)(3))	FDA 3541	218	1	218	0.25	55
Standards (807.87(d) and (f))	FDA 3654	2,700	1	2,700	10	27,000
510(k) statement (807.93)		225	10	2,250	10	22,500
Total						358,633

12b. Annualized Cost Burden Estimate

FDA believes that the average cost to industry per hour for this type of work is $67. This is based on May 2015 wage estimates issued by the Bureau of Labor Statistics (http://www.bls.gov/oes/current/oes_nat.htm) for the "Marketing Manager" and "Lawyer" occupations (occupation codes 11-2021 and 23-1011, respectively). Therefore, FDA estimates the total annual reporting cost to industry for 510(k) submissions is 358,633 total hours multiplied by $67 per hour equals $24,028,411. When divided by 3,900 submissions, this is an average of $6,161 per submission.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

FDA estimates that a total of 250 full time equivalent (FTE) positions consisting of a combination of medical officers, dental officers, scientific, and engineering professionals and support staff are required for premarket notification review and processing. An average full time equivalent (FTE) employee is projected to cost FDA's Center for Devices and Radiological Health (CDRH) $213,944 (rounded),* which consists of the employee's salary and any overhead which accompanies that employee. Therefore, the burden to government of this information collection is projected to cost approximately $53,486,000 per year ($213,944 x 250 FTEs).

*Based on the FY 2017 FDA Budget Request – Executive Summary – All Purpose Table table.

15. Explanation for Program Changes or Adjustments

There are no adjustments or program changes to this request for extension. However, we note that ROCIS database is inconsistent with the number of burden hours in the previous Supporting Statement (approved 1/3/2014, supporting statement states 358,633 hours, ROCIS states 334,827 hours). Upon submitting this Supporting Statement, we will correct the error in ROCIS. Additionally, while the corrected burden estimate takes into account the no-material/non-substantive change requests submitted since the 2014 approval, we believe it is not necessary at this time to change our overall burden estimate based on the previously approved non-substantive changes, which represent a very small portion of the overall respondents to the collection. Therefore, continue to estimate the total annual burden as 358,633 hours.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not intend to publish or tabulate the results of this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not requesting an exemption for display of the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.